MAY 12 2010

K093087

510(k) SUMMARY

The Summary of Safety and Effectiveness on the LiteCure, LLC BWF-5 Medical Laser Series reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	LiteCure, LLC 250 Corporate Blvd., Suite B Newark, Delaware 19702 Tel: 302-709-0408
Date	April 02, 2010
Correspondent	Liang Lu, Regulatory Affairs Manager
Device Name	BWF-5 Medical Laser Series
Classification	Laser surgical instrument for use in general and plastic surgery and in dermatology, 21 CFR 878.4810
Predicate Device	• K053540 INTERmedic Arfran, S.A., INTERmedic Diode Laser Family 810 nm and 980 nm and the delivery accessories that are used with them to deliver, ultrasound and RF Surgical 15™, 30™, 50™, 100™, 120™ and SR 15 OFT™, MULTIDIODE PL3D™, ContrAge™, RF ContrAge™,MULTIDIODE VARIUS™, VR1000™, MULTIDIODE ODONT™; • K082263 Biolitec, Inc., Ceralas E 980nm Diode Laser (Models E15/980, E30/980); • K083613 QUANTA SYSTEM POLYSURGE DIODE LASER FAMILY; • K060304 BioTex, Inc., PhoTex 15 Diode Laser Series: 810, 940, 980, market clearance date March 21, 2006; and • K972575 Laserscope, 800 Series Surgical Laser System Orion Surgical Laser System Angled Delivery Devices (ADD Family Product Line), market clearance date July 17, 1998. • K062363 B&W Tek, Inc., BWF-5 Medical Laser Series. • K060033 Sciton, Inc., Profile Multi-Platform System. • K071295 Biolitec, Inc., 100W CERALAS D 980NM DIODE LASER • K070388 Sciton, Inc., Profile Multi-Platform System
Intended Use	The BWF-5 Medical Laser Series (810nm, 930nm, 980nm, 1080nm and 1320nm) are intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The BWF-5 Medical Laser Series are generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery and thoracic surgery. The device is specifically indicated for use as follows:

510(k) SUMMARY continued

The Summary of Safety and Effectiveness on the LiteCure, LLC BWF-5 Medical Laser Series reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Intended Use (continued)	**LASER 980nm:** Indicated for use with the VARI-LASE Procedure Kit in the Endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux. **LASER 1320nm:** Indicated for use with the VARI-LASE Procedure Kit in the treatment of reflux of great saphenous veins associated with varicose veins and varicosities.
Description	BWF-5 Medical Laser Series are compact medical laser systems. The laser light delivery system consists of a flexible optical fiber. Activation occurs when the operator enables the laser and presses the foot switch. Release the foot switch to deactivate the laser. Depending on laser system configuration, the foot switch can function as on/off switch. A touch-screen display panel allows the operator to adjust or set laser output level. The laser can operate in continuous wave mode or controlled pulse mode.
Technological Characteristics and Substantial Equivalence	The BWF-5 Medical Laser Series is as safe and effective as the predicate devices. The BWF-5 Medical Laser Series has the same intended uses and similar indications, technological characteristics (such as wavelength, laser safety class, etc), and principles of operation as its predicate device. The minor technological differences between the BWF-5 Medical Laser Series and its predicate devices raise no new issues of safety or effectiveness. Thus, the BWF-5 Medical Laser Series is substantially equivalent to its predicate devices.
Compliance	21 C.F.R. § 1040.10 & 1040.11 Performance Standards for Light Emitting Products; IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995 (2nd Edition); IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests (Edition 2:2001 with Amendment 1:2004); IEC 60601-2-22 1995, 2nd Edition, "Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment" IEC 60825-1 Ed. 2.0 (2007), Safety of laser products - Part 1: Equipment classification, and requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

LiteCure, LLC
% Intertek Testing Services
Mr. Jay Y. Kogoma
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

MAY 12 2010

Re: K093087
Trade/Device Name: BWF-5 Medical Laser Series
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and Plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: May 05, 2010
Received: May 07, 2010

Dear Mr. Kogoma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

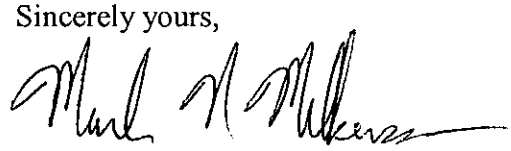
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):_____

Device Name BWF-5 Medical Laser Series

Indications For Use:

The BWF-5 Medical Laser Series (810nm, 930nm, 980nm, 1080nm and 1320nm) are intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The BWF-5 Medical Laser Series are generally indicated for incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery and thoracic surgery.

The device is specifically indicated for use as follows:

LASER 980nm:

Indicated for use with the VARI-LASE Procedure Kit in the Endovascular coagulation of the Greater Saphenous Vein (GSV) of the thigh in patients with Superficial Vein Reflux.

LASER 1320nm:

Indicated for use with the VARI-LASE Procedure Kit in the treatment of reflux of great saphenous veins associated with varicose veins and varicosities.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093087